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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
KALINOWSKI, ALEXANDER G	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Requirement for Information Under 37 C.F.R. §1.105

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. The information is required to identify products and/or services embodying the disclosed subject matter of a method and system of managing the risk of surgical site infection. The Examiner upon conducting a search for prior art, discovered web site articles describing services which lower surgical site infections that are provided by 3M (a copies of the article is attached to this request). The first article, Infection Control Rounds, Vol. 1-99, No. 3 (available in 1999), discloses a sterilization assurance program which monitors and documents the entire sterilization process. The article indicates the service was available to the public on 1/1999. Furthermore, information available from the 3m web site also refers to similar or the same services that reduce the rate of surgical site infections (3M Infection Prevention web page and #M Sterilization Assurance web page). In response to this requirement please provide any known publications, brochures, manuals and press releases that describe the Infection Control service or related services that were described by the articles.

3. The fee and certification requirements of 37 C.F.R. 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 C.F.R. 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 C.F.R. 1.105 are subject to the fee and certification requirements of 37 C.F.R. 1.97.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

5. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete response to the requirement for that item.

6. This requirement is subject to the provisions of 37 C.F.R. 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 872-9306 (for official communications including After Final communications labeled □Box AF□).

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

Alexander Kalinowski

Patent Examiner

Art Unit 3626

9/6/2004

Infection Control
ROUNDS
Vol. 1-99, No.3

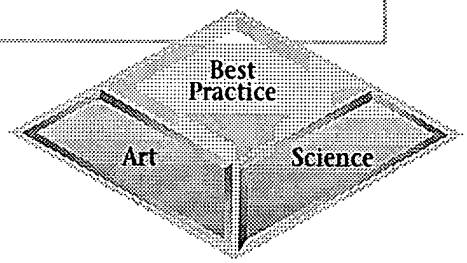
In this issue:

Evaluation of Composite Dressings on Post-operative Wounds: Clinical outcomes, cost-effectiveness, and labor savings

by Ann Marie Kahl, RN, BSN CWCN, CWOCN,
Spalding Regional Hospital, Griffin, Georgia

Controlling the Spread of Infections – *The Role of Environmental Cleaning*

by Mary Brachman RN, MS, CIC



Route to:

3M Health Care

3M Infection Prevention: This may be your best shield against infection.

Sterilization Assurance
Biological Indicators
and Test Packs
Chemical Integrators
and Indicators
Bowie-Dick Test Packs
Indicator Tapes
and Instrument Protectors
Record Keeping
Low Temperature
Sterilizer Systems

Skin Prep
Hair Removal
Patient Surgical Prep

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Antimicrobial and Incise Drape
Fluid Collection Drapes
Fabric Drapes
Equipment Drapes
Plastic Drapes
Respirators and Masks

Post-Incision Management
Staplers
Adhesive Wound Closures
Island Dressings
Self-Adherent Wrap
Surgical Tapes
Skin Protectant
Transparent Dressings
Hydrocolloid Dressings

Environmental Cleaning
Environmental Surfaces

Infection Control Rounds

Contents

3M Infection Control Rounds is made available at no charge, compliments of 3M Health Care, to health care professionals involved in infection prevention. The objective of this publication is to build awareness of the strategies and best practices for managing the risks of disease transmission and for progressive approaches to infection control. 3M is committed to providing current and reliable infection control information and educational opportunities to health care professionals.

Evaluation of Composite Dressings on Post-operative Wounds: Clinical outcomes, cost-effectiveness, and labor savings

by Ann Marie Kahl, RN, BSN CWCN, CWOCN, Spalding Regional Hospital, Griffin, Georgia

Overview

Commercially made all-in-one composite dressings, sometimes referred to as island dressings, are now available in a wide assortment of sizes and backings from several manufacturers. Composite dressings are suitable for use in most health care settings including treatments for acute wounds in emergency care (cuts, burns, and abrasions), surgery (surgical incisions), and intensive care (I.V. catheter sites), as well as chronic wounds (superficial and partial thickness wounds) in long-term care.

A comparison of all-in-one composite (island) dressings to traditional "pad/gauze/tape" dressings in an actual hospital operating room setting is necessary to establish the value of each for:

- patient outcomes
- nursing time
- convenience
- cost comparisons

Objective

The purpose of this study was to evaluate the post-operative use of a composite dressing on patients undergoing general surgery by measuring clinical outcomes, labor savings and cost-effectiveness. Post-operative periwound blistering, a problem seen with traditional dressings, was the primary clinical outcome to be evaluated with the new all-in-one composite dressing. Cost-effectiveness was to be evaluated by comparing the product costs and labor costs for traditional dressings to composite dressings used according to current hospital protocol.

Methodology

To determine standard dressing practice in the OR prior to initiating the composite dressing evaluation, 16 general surgeries were observed by the CWOCN and an assistant. They documented the types of dressings applied after various surgical procedures, the application techniques used, and the length of time for application of the dressings. Seven types of dressings were evaluated by the CWOCN on the first post-operative day.

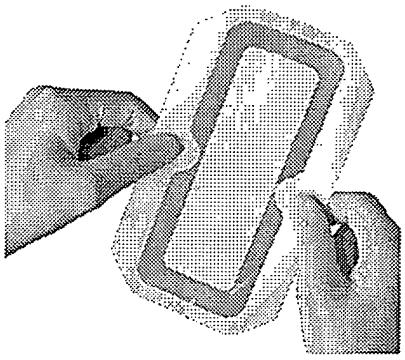


Figure 1: 3M™ Tegaderm™ +Pad Transparent Dressing with Absorbent Pad.

3M™ Tegaderm™ +Pad Transparent Dressing with Absorbent Pad (four different sizes) was selected as the composite dressing for evaluation. The operating room (OR) staff was already familiar with the Tegaderm transparent dressing with pad, and they knew, based on past experience, that it did not cause periwound blistering. The standard protocol post-operative dressing consisted of a non-adherent pad or gauze secured with tape.

One hundred twenty-five composite dressings were available for use on inpatient and outpatient surgeries. During the evaluation period, the CWOCN and assistant observed placement of the composite dressings on the surgical incisions immediately after surgery. The composite dressings were evaluated by participating staff from both the surgical unit and the postpartum unit. The evaluating staff was instructed to change the composite dressing on the fourth post-operative day unless the physician requested it to be changed sooner. Eight of the surgical inpatients were followed daily by the CWOCN to monitor the dressings during wear and to assess the periwound skin integrity upon dressing removal. Approximately 100 outpatients of the surgical and OB/GYN units were discharged with island dressings following their surgical procedures.

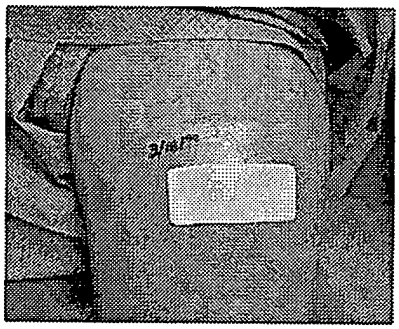


Figure 2: 3M™ Tegaderm™ +Pad Transparent Dressing with Absorbent Pad covering upper left arm mole excision site and five stitches. Day 4 – Dressing still intact after four showers.

The outpatients were instructed to remove their dressings on the fourth post-operative day. Physicians agreed to report any periwound blistering observed in the follow-up office visit.

The OR staff assisted in the cost analysis of dressing supplies for their current protocol (including supplies sent home with patients for daily dressing changes), versus supplies used in the composite dressing protocol. The CWOCN evaluated labor cost based upon their current practice of daily dressing changes versus the labor cost savings associated with up to four-day wear of the composite dressing.

Results

Prestudy OR Observations:

- OR staff was "strapping" the tape—a possible cause of periwound blisters
- OR staff was making their own composite dressings (pads/gauze/tape)
- Dressings made with gauze were bulky on the patient
- Composite dressings took less time to apply than gauze/tape dressings

Composite Dressing Trial Observations:

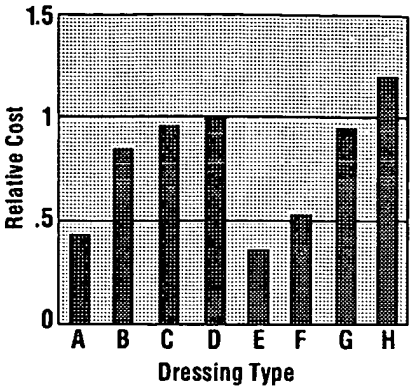
- Composite dressings took less time to apply (than current standard protocol dressings)
- Sterile delivery—composite dressing could usually be applied within the draped area
- Periwound benefits:
  - No periwound maceration
  - Absorbent pad did not adhere
  - No periwound blistering
  - Transparency allowed for periwound observation
- Patients were able to shower with the composite dressings
- Nursing time for documentation of daily dressing changes was decreased when the dressings remained in place up to four days

Financial Observations:

- The cost of supplies for the two most utilized sizes of composite dressings was less than the cost of supplies for the standard protocol dressings
- There were no nursing labor or supply costs associated with daily dressing changes when the dressing remained in place up to four days

Conclusions

The Tegaderm +pad dressing with absorbent pad provided positive clinical outcomes when utilized as a dressing for post-operative surgical incisions. This composite (island) dressing eliminated the incidence of periwound blistering, decreased the amount of nursing time spent on dressing application and changes, and showed cost savings when compared to the standard protocol dressing.



A: 2-3/8 in. x 2-3/4 in. 3M™ Tegaderm™ Transparent Dressing
B: 4 in. x 4-3/4 in. Tegaderm dressing
C: 4 in. x 4 in. Gauze/tape
D: 4 in. x 4 in. Gauze/tape/Telfa® Dressing (standard dressing relative cost=1)
E: 2 in. x 2-3/4 in. 3M™ Tegaderm™ +Pad Transparent Dressing with Absorbent Pad
F: 3-1/2 in. x 6 in. Tegaderm +pad dressing
G: 3-1/2 in. x 10 in. Tegaderm +pad dressing
H: 3-1/2 in. x 13-3/4 in. Tegaderm +pad dressing

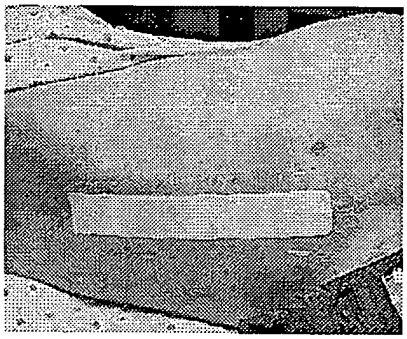


Figure 3: 3M™ Tegaderm™ +Pad Transparent Dressing with Absorbent Pad securing an epidural catheter. This photo is a representation of product usage.

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Controlling the Spread of Infections – *The Role of Environmental Cleaning*

by Mary Brachman RN, MS, CIC

Health care professionals and environmental service personnel are becoming increasingly concerned about antibiotic-resistant organisms. Evidence indicates the environment plays a limited role in the transmission of infection; however, the role it does play is crucial and reinforces the need to control transmission within health care settings. Because of this, there is an increased focus on cleaning procedures.

Unfortunately, there is often a wide variation between disciplines and facilities as to what are the correct procedures. To further complicate matters, variation and ambiguity between regulations and accreditation standards also exist. These discrepancies often lead some facilities to develop cleaning routines that increase cost without adding value.

Following is information that explores how health care facilities can decrease costs while increasing the efficiency and effectiveness of cleaning procedures. Additionally, this article addresses important aspects of the environment, including how infections are spread, who is at risk, what are appropriate disinfection levels, how susceptible are microorganisms to disinfectants, and why some cleaning procedures are controversial.

To understand how infections are transmitted, it is important to look at the six elements that must be present in order for an infection to occur and who is most at risk to infectious agents.

- *Infectious Agents (microorganisms)* – A bacteria, virus, fungus or parasite must be present.
- *Reservoirs* – Microorganisms must have a place where infectious agents survive, grow and multiply.
- *Portals of Exit* – An infectious agent must have a path in which it can leave the reservoir, such as the respiratory tract.
- *Transmission Modes* – The infectious agent must have a mechanism by which it gets from the reservoir to a susceptible person.
- *Portals of Entry* – An infectious agent must have a path in which it enters the susceptible person, such as a break in the skin, the eyes or the mouth.
- *Susceptible Host* – People who are most susceptible to infectious agents are the elderly, newborns or persons with weakened immune systems.

Environmental service personnel play a key role in breaking the chain of infection. They protect patients and coworkers by containing, controlling and eliminating reservoirs, such as cleaning medical equipment and hand contact surfaces.

Levels of Disinfection

Choosing disinfectants for environmental cleaning is a decision that should be made with input from environmental services, infection control, purchasing, and materials management personnel. In order to determine the level of disinfection needed for a particular item or surface, patient care items are divided into three categories:

- *Critical items* – Items that enter sterile tissue or the vascular system.
- *Semi-critical items* – Items that come into contact with mucous membranes or non-intact skin but generally do not penetrate the body.
- *Non-critical items* – Items that come into contact with intact skin but not mucous membranes.

The Center for Disease Control (CDC) has further expanded non-critical items to include environmental surfaces, which are surfaces that do not ordinarily come in direct contact with patients. Housekeeping surfaces include items such as floors and walls and medical equipment surfaces include items such as adjustment knobs or blood pressure cuffs.

Along with the categorization of medical equipment and environmental surfaces, there are three different levels of disinfectant activity – high, intermediate, and low. The level of disinfection needed for a particular item is based on two factors: the risk of infection associated with the use or contact of an item, and the type of microorganism to be killed.

Disinfection Factors

The activity of disinfectants against microorganisms depends on both the natural resistance of the organism as well as the chemical and physical environment. Key factors influencing the effectiveness of disinfection are:

- The number and location of organisms,
- The resistance of the microorganism,
- The concentration of solutions,
- The physical and chemical factors,
- The organic matter, and
- The contact time.

Ideal Disinfectants

In choosing a disinfectant, consider the category of the item to be disinfected, the level or disinfection needed for the particular item and the type of microorganisms that needs to be killed. Characteristics that should be taken into account when selecting a disinfectant, include:

- The broad spectrum of anti-microbial killing agents,
- The ability to rapidly kill or reduce the number of organisms,
- Whether it contains good cleaning properties,
- The surface compatibility as to not corrode or deteriorate surfaces or materials,
- Whether it's active in the presence of organic matter and compatible with other chemicals used,
- Whether the disinfectant leaves any residue on the treated surface,
- Whether it is water soluble,
- Whether it is stable in concentrate and use-dilution,
- Whether it is easy to use,
- Whether it is economical.

Controlling antibiotic resistant organisms (RO) is important because: infections are difficult to treat or there is no treatment; patient outcomes may be poor with some patients dying from untreatable infections; patient transfers to other health care settings are often delayed or denied; and the cost of care often increases.

CDC Recommendations

It's the cleaning process rather than the cleaning product that is most important to control environmental transmissions of ROs. Therefore, it is critical that personnel identify surfaces that are frequently touched, determine the frequency of cleaning, establish accountabilities and monitor compliance. The CDC recommends taking the following precautions for environmental cleaning.

Standard Precautions

- Ensure that there are adequate procedures for cleaning and disinfecting environmental surfaces, such as beds, bed rails, bedside equipment and other frequently touched surfaces.
- Ensure that reusable equipment is appropriately cleaned before it is used to care for another patient.
- Keep housekeeping surfaces and non-critical equipment clean with detergent and warm water.

Airborne Precautions

- Airborne germs are very small and stay suspended in the air for long periods; therefore, rooms should be thoroughly cleaned by applying the same techniques that are used when cleaning other patient rooms.

Droplet Precautions

- Droplets are put into the air when a person talks or coughs. To clean rooms, apply the same techniques used for cleaning other patient rooms.

Contact Precautions

- Rooms become contaminated when a patient's body fluids are not contained. Surfaces in these rooms should be cleaned daily with a low-level disinfectant.

Adding Value

To add value to your organization, take time to evaluate old practices and consider costs for implementing new methods. Whenever possible, practices should be based on scientific data that have been demonstrated effective in preventing or controlling infection. If no scientific data is available, practices should be based on consensus of experts and reasonable practices.

When evaluating costs, consider the direct costs, such as the salaries of those who clean and maintain surfaces; the fixed costs, such as the cleaning materials and supplies needed; and the variable costs, such as the equipment and products needed to maintain surfaces. Indirect costs cannot be overlooked either. These expenses include supervising and training personnel and the problems associated with disinfecting procedures, such as the deterioration of surfaces and customer satisfaction.

Changing Trends

In the past, we've seen centralized cleaning, multiple product choices, numerous policies and procedures, inefficient and ineffective training, and cleaning procedures performed

inadequately. Going forward, we can expect to see just the opposite. Training will become decentralized, products and procedures standardized, and innovative training methods implemented, which will help improve the efficiency and effectiveness of the entire cleaning process.

About the Author

Mary Brachman is an infection control educational consultant who assisted in the development of the 3M™ Commercial Care Division Employee Education and Training Program. Prior to starting her own business, Mary was the director of Infection Control at Abbott Northwestern Hospital, a 500-bed tertiary care hospital in Minneapolis, Minn. She is certified in infection control, faculty for the APIC Training Course and also faculty for the preparation course to become certified in Infection Control.

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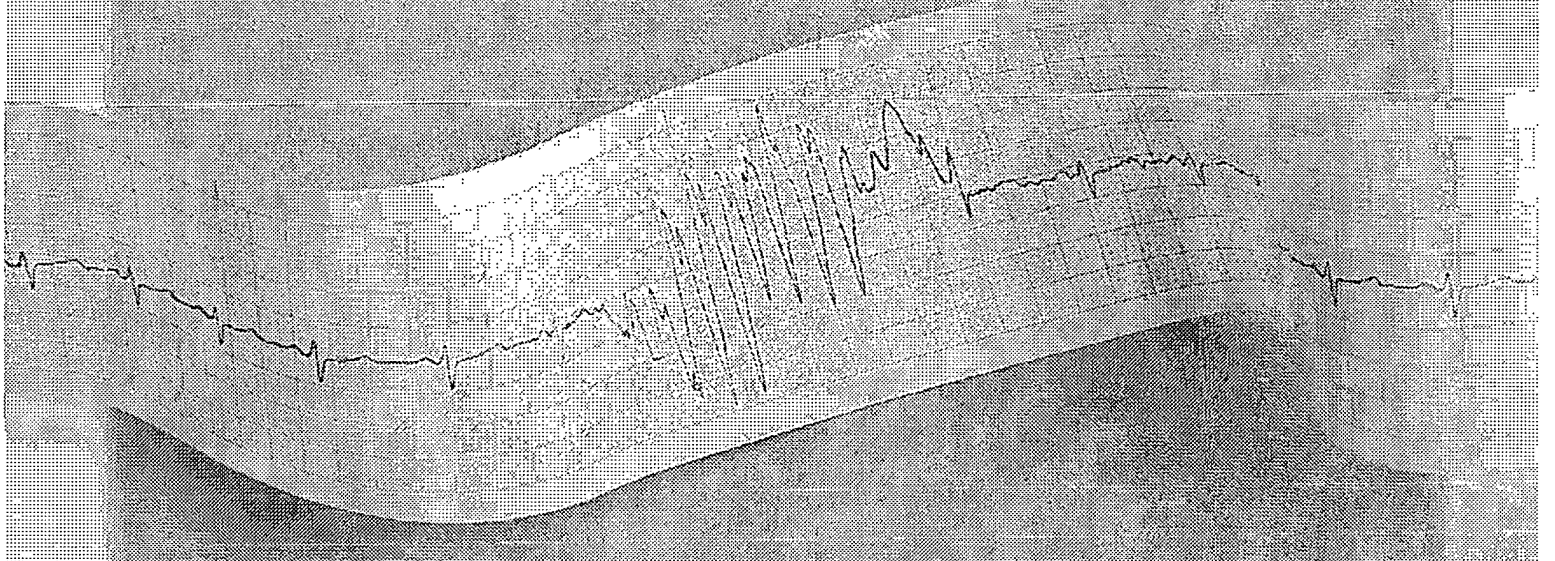
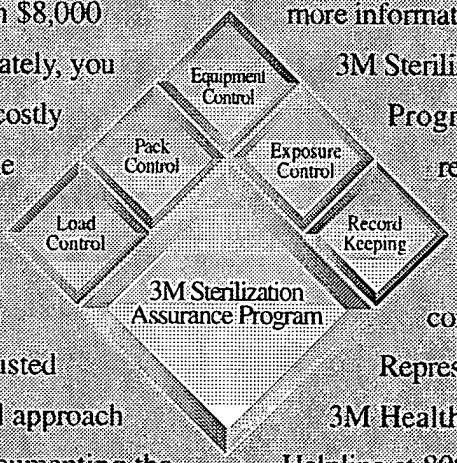
Notes

Notes

This can only mean one thing. A hospital executive just learned about a sterilization failure.



Hospital infections cost the U.S. health care system more than $8,000 every minute.* Fortunately, you can reduce the risk of costly infections by using the 3M Sterilization Assurance Program. This comprehensive program, featuring trusted products, is a practical approach to monitoring and documenting the entire sterilization process. For more information on how the 3M Sterilization Assurance Program can help you reduce the risk of infection and eliminate recalls, contact your 3M Sales Representative or call the 3M Health Care Customer Helpline at 800-228-3957.



*SOURCE: Centers for Disease Control and Prevention

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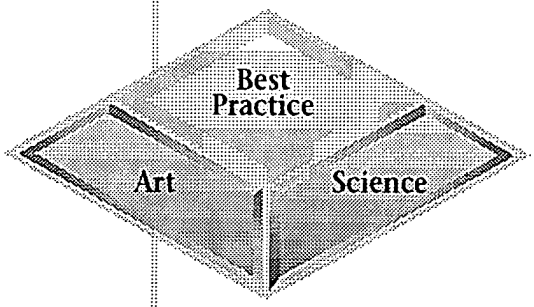

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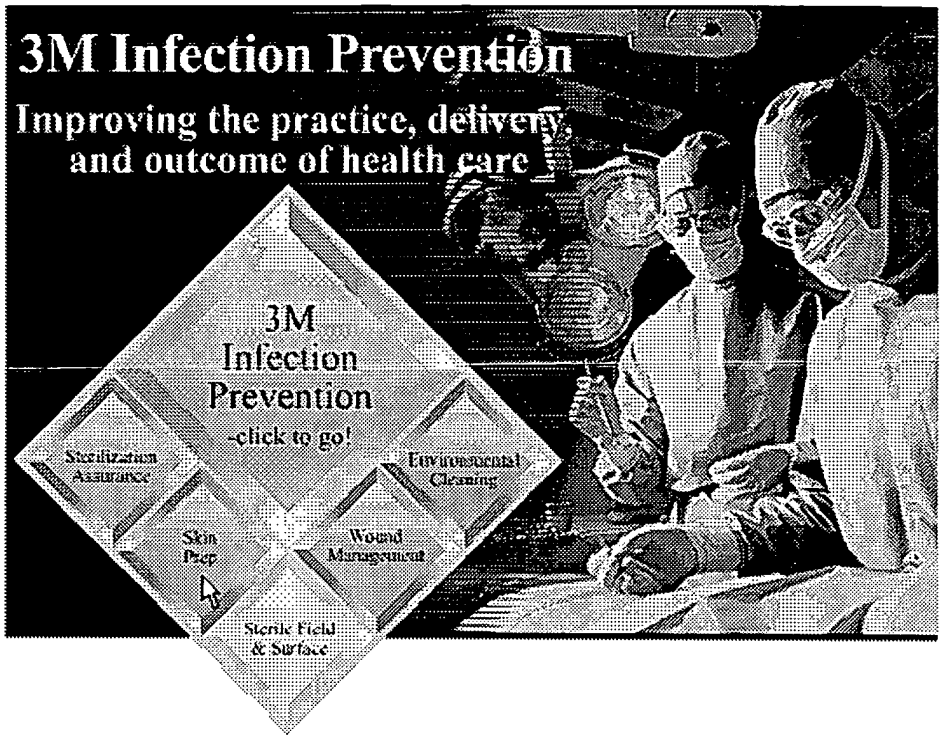


SARS Information

Information and resources regarding Severe Acute Respiratory Syndrome (SARS).

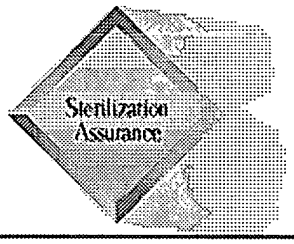
3M N95 Respirator Product Information

3M Perioperative Consulting Service

3M introduces services that help you lower the rate of surgical site infections and reduce overall costs.

New CDC Gui for Hand Hyg

CDC emphasize hand hygiene p healthcare wor reduce transm pathogenic mic to patients and

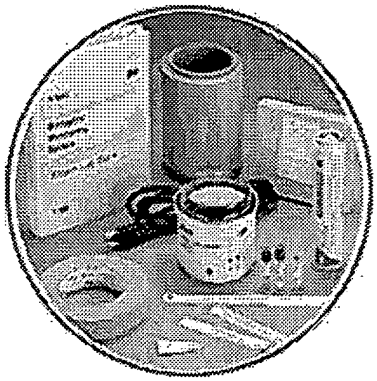


A comprehensive and practical approach to ***sterilization*** *monitoring*

Sterilization Assurance

The 3M sterilization assurance program consists of five separate, but interrelated steps:

- Load Control
- Pack Control
- Equipment Control
- Exposure Control
- Record Keeping



Together they help monitor the quality of sterilization procedures throughout the medical facility.

Why is Sterilization Assurance important?

CDC: "Inadequate sterilization of surgical instruments has resulted in Surgical Site Infection (SSI) outbreaks," according to the 1999 U.S. Centers for Disease Control (CDC) Guideline For Prevention of Surgical Site Infection. "Surgical instruments can be sterilized by steam under pressure, dry heat, ethylene oxide, or other approved methods. The importance of routinely monitoring the quality of sterilization procedures has been established. Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator."

View the complete CDC document (PDF 270kb)

Guideline for Prevention of Surgical Site Infection, 1999, Centers for Disease Control and Prevention, p. 261.

Product So

- 3M™ Attest Biological In
- 3M™ Comp Indicators
- 3M™ Comp Plus Test Pa
- 3M™ Comp Tape
- 3M™ Sterili Record Kee
- 3M™ Steri-Sterilization
- Sterilization
- Low Tempe Sterilization

Educationa

- Issues & An